

**510(k) SUMMARY****Versalok Anchor****DEC 15 2006****Submitter's Name and Address:**

DePuy Mitek  
a Johnson & Johnson company  
325 Paramount Drive  
Raynham, MA 02767

**Contact Person**

Ruth C. Forstadt  
Project Management Lead, Regulatory Affairs  
DePuy Mitek  
a Johnson & Johnson company  
325 Paramount Drive  
Raynham, MA 02767  
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**Name of Medical Device**

Classification Name: Fastener, Fixation, Nondegradable, Soft  
Tissue Smooth or threaded metallic bone  
fixation fasteners

Common/Usual Name: Bone Anchor

Proprietary Name: Versalok Anchor

**Substantial Equivalence**

Versalok Anchor is substantially equivalent to:

Trident Anchor (K060914)

**Device Classification**

The Versalok Anchor device carries an FDA product code MBI and HWC, and is classified as Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners under 21 CFR 888.3040.

Sutures, classified by the FDA, are Class II Medical Devices. The sutures (that are provided with the anchor) are classified as follows:

Orthocord suture (a combination of PDS and Polyethylene suture):

PDS Suture carries an FDA product code NEW, and is classified as absorbable surgical suture, polydioxanone under 21 CFR 878.4840.

Polyethylene suture carries an FDA product code GAT, and is classified under 21 CFR 878.5000.

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Panacryl Suture carries an FDA product code NEW, and is classified as suture, absorbable synthetic polyglycolic acid under 21 CFR 878.4493.

Ethibond suture carries an FDA product code of GAS, and is classified as suture, non-absorbable synthetic polyester under 21 CFR 878.5000.

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**Device Description**

The Versalok Anchor System includes the Versalok Anchor, which will be presented sterile, pre-mounted on an inserter shaft w/anvil with a threader tab and suture. The System will be deployed with the use of a reusable Deployment Gun. The system could be provided with a variety of #2 suture options.

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**Indications for Use**

The Versalok Anchor is indicated for use in the following:

**Shoulder:** Rotator Cuff Repair, Biceps Tenodesis,

**Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; Joint Capsule Closure

**Elbow:** Biceps Tendon Reattachment

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**Safety and Performance**

Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Versalok Anchor has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 15 2006

DePuy Mitek  
% Ruth C. Forstadt, RAC  
Project Management Lead,  
Regulatory Affairs  
Raynham, Massachusetts 02767

Re: K063478

Trade/Device Name: Versalok Anchor  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulation Class: II  
Product Code: HWC, MBI, NEW, GAT, GAS, GAM  
Dated: November 16, 2006  
Received: November 17, 2006

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ruth C. Forstadt, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): \_\_\_\_\_

Device Names: Versalok Anchor

VERSALOK Anchor is indicated for use in the following:

Shoulder: Rotator Cuff Repair, Biceps Tenodesis

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; Joint Capsule Closure

Elbow: Biceps Tendon Reattachment



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices510(k) Number K063478Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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